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Network Rave Data Standards (NRDS)
Policy and Governance WG
Kick-Off Meeting

Judi Manola and Mike Montello
April 20th, 2015

Agenda

- Introductions

- Benefits of Standards

- Goals

- Deliverables

- Logistics

- NRDS Working Groups

- Next Steps

Policy and Governance Working Group Members

Organization	Representative
Alliance	Shauna Hillman
Alliance	Katie Allen Ziegler
ECOG-ACRIN	Judy Manola*
NRG	Jennifer Thomas
Theradex	Diana Vulih
Theradex	Pam Rapoport
COG	Steven Jong
COG	Thalia Beeles

Organization	Representative
SWOG	Rodney Sutter
SWOG	Angela Smith
NCI	Mike Montello*
NCI	Andrea Denicoff
NCI	Dianne Reeves
NCI	Janice Chilli
NCI	Neesha Desai

How is this different from other CDE activities?

caDSR/CRF Roadmap

- Audience:
  - Entire NCI research community
- CDMS:
  - Agnostic
- Emphasis (caDSR):
  - Repository (vs. standards)
- Leadership:
  - NCI led
- Development:
  - 'Theoretical exercise'
- Implementation Plan
  - Loosely defined

NRDS

- Audience:
  - NCTN, ETCTN & NCORP (step 2)
- CDMS:
  - Rave first
- Emphasis
  - Standardization
- Leadership:
  - NCI/Network co-led
- Development:
  - Practical use
- Implementation Plan
  - Comprehensive

Case Report Forms and Components of a Standardized CDEs

- Case Report Forms
  - Standardize where the CDE is placed on the form and how those forms are organized. This will impact the ability to integrate.

- If question asked:
  - Should ALWAYS be asked the same way*

- Response <u>User</u> Value
  - Pick list <u>should be comprehensive</u> BUT 'make sense' business rules allow exceptions

- Response <u>Coded</u> Value
  - Each User value shall be paired with a coded value (ex. No = 0).
  - Policy for utilization TBD.

Benefits of Data Standards

- **Support Science**
  - Primary study
  - Re-use for Correlative studies
  - Re-use for Meta-Analysis
- **Promote patient safety**
  - Routine and serious AE reporting
- **Reduce research burden** on entire research community
  - Streamline Rave study build process
  - Simplify data entry/capture for local investigators and research staff
  - Maximize opportunity for system integration

Working Group Goals

- Identify requirements to guide decisions on the adoption and usage of the standardized CDEs by NCTN and ETCTN.

- Define an interim policy on the usage of the set of standardized CDEs
  - This policy will be completed in an iterative approach

- Establish principles, responsibilities and requirements for development, maintenance and implementation of standards governance policies within NTCTN and ETCTN
  - Identify a process for divergence (the exception not the rule)

- Establish compliance methodology for the use of the CDEs in Rave within NTCTN and ETCTN

Working Group Deliverables

- Interim policy for the 1st phase of implementation
    - List of policy guidelines to support decisions on the adoption and usage of the standardized CDEs by NCTN and ETCTN

- Timeline for adoption (phased approach)

- Governance plan including the following:
    - Set of principles for the governance framework around data maintenance and storage
        - Organizational, Trust, Business and Technical
    - Roles and responsibilities for maintenance of standards within NCTN/ETCTN
    - Development of Standard Operations Procedures (SOPs) and Best Practices
    - Define a compliance methodology for the use of the identified CDEs in Rave
    - Development the process to handle exceptions to policies (rare)

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Policy Working Group Logistics

- Meetings will be held twice a month

- Judi Manola and Mike Montello will co-lead the working group activities

- Neesha Desai, CRF Project Manager, will provide project management support to complete the project

- Brenda Maeske, WG Curator, will provide support in curation activities

- All documentation will be posted on the [NRDS Policy WG Wiki](#)

Policy Working Group Wiki

- Access to wiki

  - https://wiki.nci.nih.gov/display/NNRDSC/Policy+and+Governance+Working+Group

- Purpose

  - Provide a centralized place to manage and document Content WG activity

  - Working group lead contact and meeting information

  - Calendar of meetings

  - Working group project documentation

  - Working group rosters

- Neesha Desai will manage and maintain the wiki site

Membership / Expectations

- Working Group Expectations
    - Each member represents an organization
    - Meet goals and deliverables of the workgroup
    - Value the input from each attendee
    - Maintain an energetic and courteous environment
    - Active participation
    - Advance notification of meeting absence

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Next Steps

- Discuss the operational and functional objectives of the project
  - Support common analyses across trials
  - Harmonizing with integration activities
- Define list of requirements to guide usage on the adoption and usage of the standardized CDEs by NCTN and ETCTN
- Identify a NCTN/ETCTN co-lead for the NRDS Committee
- Identify a recurring meeting time

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Other NRDS Working Groups

- Content Working Group
  - Define a process to identify and prioritize the content that will be reviewed in the NRDS Content WG.
    - Consensus building will be used to reach agreement on content areas.

  - Identify the first set of CDEs for use in Rave by NCTN and ETCTN

- Training and Communication Working Group
  - Define the requirements and key components of a training plan for NCTN/ETCTN
    - Training for implementation of the 1st set of identified CDEs in Rave

  - Define the roles and responsibilities of NRDS Committee project participants in the review, approval and dissemination of information about key project processes, events, documents and milestones

Reference Information / Questions

- NCTN Co-Lead
  - Judith Manola, M.S., Biostatistician, Department of Biostatistics and Computational Biology, Dana-Farber Cancer Institute
  - jmanola@jimmy.harvard.edu

- NCI Co-Lead
  - Mike Montello, PharmD, MBA
    Associate Branch Chief for Clinical Trials Technology
  - montellom@mail.nih.gov

- Project Management Support
  - Neesha Desai, PMP, Project Manager, NCI CBIIT
  - Neesha.Desai@nih.gov

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Potential methodologies to identify NRD CDEs

- Leverage Prior Experience
  - Rave – Previously developed reusable Rave eCRFs developed by the Network Groups and Theradex
  - CRF Roadmap
  - caDSR
  - Data Elements Working Group (DEWG)
  - Pre-Rave Phase 3 CDE Validation by EMMES
  - Disease/therapy
    - BOLD
- Data driven identification of potential CDEs – ID highest frequency:
  - Publication
  - Meta-analysis
  - Use in Rave